

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

12-1523, 12-1524, 12-1545, 12-1546, 12-1555, 12-1556, 12-1557, 12-1566, 12-1590, 12-1591, 12-1592,
12-1596, 12-1597, 12-1598, 12-1599

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK,
Plaintiff,

and

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

and

GALDERMA LABORATORIES INC. and GALDERMA LABORATORIES, L.P.,
Plaintiffs-Cross Appellants,

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellant.

MYLAN PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

GALDERMA LABORATORIES INC. and GALDERMA LABORATORIES, L.P.,
Defendants-Cross Appellants,

and

SUPERNUS PHARMACEUTICALS, INC.,
Defendant-Appellee.

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK,
Plaintiff,

and

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

and

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

and

GALDERMA LABORATORIES INC. and GALDERMA LABORATORIES, L.P.,
Plaintiffs-Cross Appellants,

v.

IMPAX LABORATORIES, INC.,
Defendant-Appellant.

GALDERMA LABORATORIES INC. and GALDERMA LABORATORIES, L.P.,
Plaintiffs-Cross Appellants,

and

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

v.

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,
Defendants-Appellants.

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK,
Plaintiff,

and

NEW YORK UNIVERSITY,
Plaintiff-Appellant,

and

GALDERMA LABORATORIES INC. and GALDERMA LABORATORIES, L.P.,
Plaintiffs-Appellants,

v.

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,
Defendants-Cross Appellants.

Appeal from the United States District Court for the District of Delaware in case no. 09-CV-0184, 10-CV-0892 United States District Judge Leonard P. Stark.

MANDATE

In accordance with the judgment of this Court, entered August 07, 2013, and pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk

cc: Clerk of Court, District of Delaware (Wilmington)
Evan D. Diamond
Gerald J. Flattmann Jr.
Kirin K. Gill
Wendell Wade Harris
Joseph T. Jaros
Stephen Blake Kinnaird
Tung On Kong
Gregory R. Lyons
Paul J. Molino
Timothy A. Molino
William A. Rakoczy
Matthew R Reed
Melanie R. Rupert
David S. Steuer
Robert Michael Teigen
Eric Harold Weisblatt
Lorelei Perez Westin

Christine Willgoos
Andrew Peter Zappia

**United States Court of Appeals
for the Federal Circuit**

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

AND

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellant.

MYLAN PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Defendants-Cross Appellants,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Defendant-Appellee.

2012-1523, -1524, -1555, -1556, -1557

Appeals from the United States District Court for the
District of Delaware in Nos. 09-CV-0184 and 10-CV-0892,
Judge Leonard P. Stark.

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

AND

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

AND

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

v.

IMPAX LABORATORIES, INC.,
Defendant-Appellant.

2012-1545, -1546, -1590, -1591, -1592

Appeals from the United States District Court for the
District of Delaware in Nos. 09-CV-0703 and 11-CV-0477,
Judge Leonard P. Stark.

**GALDERMA LABORATORIES INC. AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

v.

**LUPIN LIMITED AND
LUPIN PHARMACEUTICALS, INC.,**
Defendants-Appellants.

2012-1566, -1596

Appeals from the United States District Court for the
District of Delaware in No. 10-CV-1112, Judge Leonard P.
Stark.

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

NEW YORK UNIVERSITY,

Plaintiff-Appellant,

AND

**GALDERMA LABORATORIES INC. AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Appellants,

v.

**LUPIN LIMITED AND
LUPIN PHARMACEUTICALS, INC.,**
Defendants-Cross Appellants.

2012-1597, -1598, -1599

Appeals from the United States District Court for the
District of Delaware in No. 09-CV-0483, Judge Leonard P.
Stark.

JUDGMENT

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

**AFFIRMED-IN-PART, VACATED-IN-PART, AND
REMANDED**

ENTERED BY ORDER OF THE COURT

August 7, 2013
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

AND

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

v.

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellant.

MYLAN PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Defendants-Cross Appellants,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Defendant-Appellee.

2012-1523, -1524, -1555, -1556, -1557

Appeals from the United States District Court for the
District of Delaware in Nos. 09-CV-0184 and 10-CV-0892,
Judge Leonard P. Stark.

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

AND

NEW YORK UNIVERSITY,
Plaintiff-Cross Appellant,

AND

**GALDERMA LABORATORIES INC., AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

v.

IMPAX LABORATORIES, INC.,
Defendant-Appellant.

RESEARCH FOUNDATION v. MYLAN PHARMACEUTICALS

3

2012-1545, -1546, -1590, -1591, -1592

Appeals from the United States District Court for the District of Delaware in Nos. 09-CV-0703 and 11-CV-0477, Judge Leonard P. Stark.

**GALDERMA LABORATORIES INC. AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Cross Appellants,

AND

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee,

v.

**LUPIN LIMITED AND
LUPIN PHARMACEUTICALS, INC.,**
Defendants-Appellants.

2012-1566, -1596

Appeals from the United States District Court for the District of Delaware in No. 10-CV-1112, Judge Leonard P. Stark.

4

RESEARCH FOUNDATION v. MYLAN PHARMACEUTICALS

**THE RESEARCH FOUNDATION OF STATE
UNIVERSITY OF NEW YORK,**
Plaintiff,

AND

NEW YORK UNIVERSITY,
Plaintiff-Appellant,

AND

**GALDERMA LABORATORIES INC. AND
GALDERMA LABORATORIES, L.P.,**
Plaintiffs-Appellants,

v.

**LUPIN LIMITED AND
LUPIN PHARMACEUTICALS, INC.,**
Defendants-Cross Appellants.

2012-1597, -1598, -1599

Appeals from the United States District Court for the
District of Delaware in No. 09-CV-0483, Judge Leonard P.
Stark.

Decided: August 7, 2013

ANDREW P. ZAPPIA, LeClairRyan, of Rochester, New
York, argued for New York University. With him on the
brief was WENDELL W. HARRIS.

GERALD J. FLATTMANN, JR., Paul Hastings LLP, of
New York, New York, argued for Galderma Laboratories

Inc., et al., and Supernus Pharmaceuticals, Inc. With him on the brief were MELANIE R. RUPERT and EVAN D. DIAMOND. Of counsel on the brief was STEPHEN B. KINNAIRD, of Washington, DC. Of counsel was CHRISTINE WILLGOOS, of New York, New York.

DAVID S. STEUER, Wilson Sonsini Goodrich & Rosati, of Palo Alto, California, argued for Mylan Pharmaceuticals Inc. With him on the brief were MATTHEW REED and KIRIN GILL. Of counsel on the brief were TUNG-ON KONG, of San Francisco, California, and LORELEI WESTIN, of San Diego, California.

WILLIAM A. RAKOCZY, Rakoczy Molino Mazzochi Siwik LLP, of Chicago, Illinois, for Lupin Limited, et al. With him on the brief were PAUL J. MOLINO, JOSEPH T. JAROS, and ROBERT M. TEIGEN.

ERIC H. WEISBLATT, Wiley Rein, LLP, of Washington, DC, for Impax Laboratories, Inc. With him on the brief was GREGORY R. LYONS.

Before NEWMAN, REYNA, and TARANTO, *Circuit Judges*.

PER CURIAM.

In related district-court actions, plaintiff Galderma Laboratories, L.P., along with other patent-asserting parties, alleged that the Abbreviated New Drug Applications submitted by Mylan Pharmaceuticals Inc., Lupin Limited, and Impax Laboratories, Inc., each constituted an act of infringement under 35 U.S.C. § 271(e)(2). After a four-day bench trial addressing five patents, the district court granted the patent-asserting parties relief on one patent: it rejected invalidity challenges to the asserted claims of that patent and held that those claims would be infringed by the proposed manufacture, use, and sale of generic versions of Oracea®. *Research Found. of State*

Univ. of New York v. Mylan Pharms. Inc., 809 F. Supp. 2d 296 (D. Del. 2011). The district court denied relief on the other patents, some of which it held invalid as to all of the asserted claims. *Id.* at 307. Appeals and cross-appeals are now before this court.

We affirm the district court in every respect, except with regard to three dependent claims of the Amin Patents, namely, claims 2 and 14 of U.S. Patent No. 5,789,395 and claim 2 of U.S. Patent No. 5,919,775. And we find only that issue to warrant discussion, given the extensive analysis of the district court. We conclude that the district court erroneously (though understandably) applied its finding of anticipation of the independent claims of the Amin Patents without addressing the additional claim elements of the three specified dependent claims. We vacate the district court's invalidity judgment as to those dependent claims and remand for further proceedings.

The Amin Patents claim methods for treating medical conditions, such as inflammatory disorders, characterized by increased endogenous nitric oxide production. Specifically, the Amin Patents claim the use of tetracyclines—a class of antibiotics that includes doxycycline—to inhibit nitric oxide production or nitric oxide synthase expression or activity. Galderma licensed the Amin Patents and, along with co-assignees New York University and the Research Foundation of the State University of New York, asserted twelve claims from the Amin Patents. Three of the dependent claims—claims 2 and 14 of the '395 patent and claim 2 of the '775 patent—require, in addition to the nitric-oxide limitations of the independent claims, that the administered “tetracycline compound has substantially no anti-microbial activity.”

During trial, Mylan identified eight prior-art references that disclosed treating periodontitis or rheumatoid arthritis, both chronic inflammatory disorders, with between 40 and 200 mg of a tetracycline daily. The district court found that the “higher dosage” prior-art

references, *i.e.*, daily tetracycline dosages between 60 and 200 mg, inherently anticipated the Amin Patents because “[t]he record shows that at these dosages . . . [nitric oxide] production or [nitric oxide synthase] expression will be inhibited.” *See Research Found.*, 809 F. Supp. 2d at 329. The district court made no findings on the prior-art references that disclosed lower tetracycline dosages, between 40 and 60 mg. *Id.* And the district court made no findings on whether any of the prior art contained the additional limitations found in the asserted dependent claims, including whether any of the eight prior-art references disclosed the limitation of claims 2 and 14 of the ’395 patent and claim 2 of the ’775 patent that the “tetracycline compound has substantially no anti-microbial activity.” *Id.*

A determination that a patent claim is invalid as anticipated under 35 U.S.C. § 102 “requires that a prior art reference disclose every limitation of the claimed invention, either explicitly or inherently.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007). What suffices to anticipate one claim may not suffice for another claim containing different elements. In particular, when a dependent claim adds an element to an independent claim, and the challenger sufficiently raises the point, an anticipation analysis must examine the additional element—which, by definition, it will not have been necessary to analyze in assessing anticipation of the independent claim not containing the added element. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370-71 (Fed. Cir. 2003).

In invalidating all of the asserted claims of the Amin Patents, the district court found that certain references inherently disclosed use of a tetracycline to inhibit endogenous nitric-oxide production, but it never determined, as required, whether those treatments also had “substantially no anti-microbial activity.” This limitation made claims 2 and 14 of the ’395 Patent and claim 2 of the ’775 Patent materially different from the independent claims

for the purpose of determining validity, and the district court erred by not addressing it.

We reject the suggestion of the patent-asserting parties that this court not only vacate but reverse on these claims, a suggestion based on the premise that the record conclusively establishes “that the four Higher Dosage References relied upon cannot meet the substantially no antimicrobial effect limitation.” Br. for New York Univ. at 44. Even if the larger dosage references did not anticipate the three dependent claims at issue for that reason—a question on which we express no view—reversal would not be appropriate because the district court made no findings about what the lower dosage references disclosed expressly or inherently. Without such findings, this court cannot rule out anticipation of the three dependent claims (let alone any other preserved grounds of invalidity of those claims). See *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1254-55 (Fed. Cir. 2008). Thus, we go no further than to vacate the invalidity judgment as to these three claims.

We do so despite readily understanding how the district court likely came to overlook the additional elements of these dependent claims. In their post-trial papers, the patent-asserting parties mentioned the additional elements of these claims in a proposed finding of fact, Galderma’s Post-Trial Proposed Findings of Fact at 23, ¶ 162 *Research Found. of State Univ. of New York*, 809 F. Supp. 2d 296 (Civ. No. 09-184), but focused their arguments on the independent claims, specifically, on whether the eight identified prior-art references inherently disclosed use of a tetracycline to inhibit endogenous nitric-oxide production. See Galderma’s Post-Trial Brief at 22-24, *Research Found. of State Univ. of New York*, 809 F. Supp. 2d 296 (Civ. No. 09-184). Despite the patent-asserting parties’ scant attention to the distinction between these dependent claims and their independent claims, however, the patent-challenging parties in this court did not argue waiver or the like, but addressed the point entirely on its

merits. Indeed, they admitted that the patent-asserting parties presented the distinct challenge to the dependent claims. See Letter from Appellant Mylan Pharmaceuticals Inc., *Research Found. of State Univ. of New York v. Mylan Pharmaceuticals Inc.*, No. 13-1047 (Fed. Cir. July 22, 2013).

For the foregoing reasons, we affirm the district court judgment except as to claims 2 and 14 of the '395 Patent and claim 2 of the '775 Patent. We vacate the district court's judgment of invalidity of those claims and remand for further proceedings consistent with this opinion.

COSTS

No costs.

**AFFIRMED-IN-PART, VACATED-IN-PART, AND
REMANDED**